

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL
INDUSTRY AVERAGE
WHOLESALE PRICE LITIGATION

)
) MDL No.1456
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THIS DOCUMENT RELATES TO:
U.S. of America ex rel. Ven-A-Care
of the Florida Keys, Inc., et al. v.
Boehringer Ingelheim Corporation, et al.,
Civil Action No. 07-10248-PBS

) Judge Patti B. Saris
)
) Magistrate Judge Marianne B. Bowler
)
)
)

**BOEHRINGER INGELHEIM CORPORATION AND BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC.'S MEMORANDUM IN SUPPORT OF THEIR MOTION
TO BIFURCATE THE CORPORATE VEIL-PIERCING ISSUES FOR TRIAL**

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INTRODUCTION

As set forth in detail in BIC and BIPI's pending Motion for Summary Judgment, this case is premised on the pricing, marketing and selling of nine *Roxane* drugs and there is insufficient evidence in the record to hold Roxane's parent company, BIC, or its sister corporation, BIPI, liable under either a direct liability or veil-piercing theory for alleged false claims related to those Roxane drugs. To the extent the Court allows the case against BIC and BIPI to proceed to trial, however, it should, at a minimum, invoke Federal Rule of Civil Procedure 42(b) and try the veil-piercing claims against BIC and BIPI separately from, and after, the trial on the underlying False Claims Act ("FCA") claims. Bifurcation will not only alleviate a serious risk of juror confusion and prejudice to BIC and BIPI, but will also promote judicial economy and efficiency.

The Government asserts two legally and factually distinct theories for holding BIC and BIPI liable for false claims related to Roxane's drugs: (1) a newly-minted direct liability theory, under which the Government asserts that BIC and BIPI were directly involved in the pricing of Roxane's drugs that caused the submission of false claims under the FCA,¹ and (2) a derivative veil-piercing theory, under which BIC and BIPI are purportedly liable, not because they participated in the underlying conduct giving rise to FCA liability, but because the corporate, financial and control relationships between the companies were such that BIC and BIPI were merely "alter-egos" of Roxane. As is evident from the summary judgment briefing on these issues,² the legal elements of proof for the Government's two theories of liability are wholly different and the relevant factual evidence is almost entirely distinct for each theory. Thus, each theory must stand or fall on its own merits. But if both theories proceed in a

¹ While the Government now presses a direct FCA liability claim against BIC and BIPI, it did not plead or otherwise assert such a theory until shortly before BIC and BIPI moved for summary judgment. *See* BIC/BIPI SJ Memo. at 14 (docket # 6192); BIC/BIPI Reply to Mot. for SJ at 8 (docket # 6516).

² The summary judgment briefs on these issues are at docket #s 6192, 6410, 6516 and 6575. The Court has not yet heard or scheduled oral argument on this motion.

single trial, the jury will undoubtedly confuse these two complicated issues, blending one into the other, and allowing evidence from one claim to potentially bolster or influence its finding on the other. As a result, there is a high risk in a trial combining both the direct FCA claims and the veil-piercing issues that the jury will improperly find BIC and BIPI liable even though neither theory of liability is factually or legally sound enough to succeed if tried on its own.

Moreover, the risk of jury confusion and prejudice is even greater in this case because the FCA and veil-piercing claims are individually complicated and highly fact-intensive. Given the complexity and overwhelming nature of the issues and evidence, described more fully below, it will be difficult enough for a jury in one trial to distinguish the direct liability and damages issues related to nine Roxane drugs for the separate entities of Roxane, BIC and BIPI, let alone evaluate the evidence and make independent determinations regarding the liability of BIC and BIPI under the separate veil-piercing theory. Of course, these difficulties and risks will only be magnified if Dey's FCA liability trial is consolidated with Roxane's trial.

Bifurcating the corporate veil-piercing claims for trial would also promote judicial economy and efficiency. Because the alter-ego theory of liability is predicated on Roxane's liability under the FCA, if a jury concludes that Roxane is not liable, the veil-piercing claims against BIC and BIPI would be mooted. Accordingly, because there will be little overlap in evidence between the two trials, holding an initial trial on the FCA claims could obviate the need for a second trial and save significant time, money and judicial resources.

BACKGROUND

I. THE VEIL-PIERCING CLAIMS AGAINST BIC AND BIPI ARE LEGALLY AND FACTUALLY DISTINCT FROM THE FCA CLAIMS AGAINST ROXANE, BIC AND BIPI.

The direct FCA liability claims against Roxane, BIC and BIPI involve different law, facts, and witnesses from the veil-piercing claims against BIC and BIPI. This Court is well aware of the strict falsity, scienter and causation elements the Government must prove to establish an FCA claim in this context. Given the legal elements, the FCA trial in this case will necessarily require evidence on at least the following issues: when and how AWP's and other prices were set and changed for the Roxane drugs at issue during the relevant ten year period; how, when and why AWP's for the subject drugs were reported and used by Medicare and Medicaid programs; Roxane's marketing practices related to the subject drugs; the extent of BIC's and BIPI's involvement, if any, in setting or reporting AWP's and marketing the Roxane drugs; the use and meaning of AWP in the pharmaceutical industry; the historical reimbursement methodologies and associated political and legislative histories of the Medicare and Medicaid programs; Roxane's knowledge of those reimbursement methodologies; the long history of Government awareness regarding the meaning and use of AWP in the industry; and the damages allegedly suffered by the Government.

An entirely separate legal and factual inquiry governs the determination of whether BIC or BIPI should be held liable for any FCA violations by Roxane because they were at relevant times the "alter-egos" of Roxane. As discussed more fully in BIC and BIPI's summary judgment briefing, to pierce the corporate veil, the Government must establish three conditions: 1) the parent and subsidiary ignored the independence of their separate operations; 2) the principal had fraudulent intent; and 3) failure to pierce the veil would result in substantial injustice. *U.S. v. Mountzoures*, 376 F. Supp. 2d 13, 18 (D. Mass. 2005); *see also* BIC/BIPI SJ Memo. at 8-14 (docket # 6192). Accordingly, the evidence that is likely to be presented in support and defense of the alter ego claims will be wide-ranging and broader in scope

than the Roxane-related evidence relevant to the underlying FCA claims. *See* BIC/BIPI SJ Memo. at 2-7 (docket # 6192); US Opp’n to BIC/BIPI Mot. for SJ at 2-9 (docket # 6410); BIC/BIPI SOF Reply generally (docket # 6517). That evidence will include: the corporate organizational structures of Roxane, BIC and BIPI over time and various re-organizations that occurred; the management and reporting relationships within and among the three companies; contracts, transactions and other interactions between the companies; the Board make-up and conduct of the various entities; the dual roles and responsibilities of specific employees and officers; the financial reporting and cash management practices of the companies; and the level of Roxane’s capitalization over time and as compared to others in the industry, including the timing and impact of specific dividend payments.

Given the distinct legal and factual issues involved in the two theories, the vast majority of the evidence applies exclusively to *either* the direct liability claims or the corporate veil-piercing issues, but not both. Thus, there is minimal overlap in the evidence, witnesses and documents that will be presented.

ARGUMENT

Federal Rule of Civil Procedure 42(b) authorizes courts to order separate trials of one or more issues or claims “[f]or convenience, to avoid prejudice, or to expedite and economize” Fed. R. Civ. P. 42(b). “Only one of these criteria need be met to justify bifurcation.” *Saxion v. Titan-C-Manufacturing, Inc.*, 86 F.3d 553, 556 (6th Cir. 1996) (citing *MCI Commc’ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1177 (7th Cir.)). Further, “[t]he decision to bifurcate ‘is committed to the sound discretion of the court.’” *Hewlett-Packard Co. v. Genrad, Inc.*, 882 F. Supp. 1141, 1157 (D. Mass. 1995) (internal citation omitted); *Acevedo-Garcia v. Monroig*, 351 F.3d 547, 558 (1st Cir. 2003) (“[C]ourts of appeals accord broad latitude to district courts in this area.”). Ordering a separate trial on the veil-piercing issues following the trial on the FCA claims will not only avoid a grave risk of prejudice to BIC and BIPI, but will also promote judicial economy and efficiency.

I. THE VEIL-PIERCING ISSUES SHOULD BE SEPARATED FOR TRIAL TO AVOID PREJUDICE.

Separate trials are necessary “to avoid prejudice, as when evidence admissible only on a certain issue may prejudice a party in the minds of the jury on other issues.” 9A Wright & Miller, Fed. Prac. § 2388 (2009); *Beeck v. Aquaslide ‘N’ Dive Corp.*, 562 F.2d 537, 541-42 (8th Cir. 1977); *Schmidt v. Cal. State Auto. Assoc.*, 127 F.R.D. 182, 185 (D. Nev. 1989) (granting defendant’s motion to sever because evidence pertaining to one of plaintiff’s claims could prejudice defendant with respect to another of plaintiff’s claims). In this case, separate trials are essential both to avoid the veil-piercing evidence prejudicing BIC and BIPI with regard to the direct liability claims against them and also to prevent the FCA evidence relating to Roxane, BIC and BIPI from causing prejudice to BIC and BIPI on the alter-ego claims. Moreover, the likelihood of jury confusion from combining trial on two independently complex issues, which each require presentation of significant evidence, increases the risk of prejudice to BIC and BIPI in this case.

A. Veil-Piercing Evidence Will Prejudice The Jury Regarding The Direct Liability Claims Against BIC and BIPI.

As discussed fully in their motion for summary judgment, even under the Government’s FCA theory, BIC and BIPI could only be liable under the FCA in their own right for claims associated with Roxane’s drugs if they actively participated in setting or reporting AWP’s for the specific drugs at issue and caused submission of false claims. *See* BIC/BIPI Reply to Mot. for SJ at 9-10. Evidence that may be pertinent to the veil piercing issues regarding the general interactions among the companies and the working relationships between BIC’s, BIPI’s and Roxane’s corporate structures, finances, and officers has no relevance to and cannot establish direct liability for BIC or BIPI. Yet, if this type of evidence is presented, the jury is likely to find it difficult to distinguish between which interactions among Roxane, BIC and BIPI support a direct liability claim and which are relevant only to the veil-piercing inquiry. The jury could thus improperly find BIC and BIPI directly liable, not because there is sufficient

evidence of their own active participation in the specific pricing and marketing activities that purportedly violate the FCA, but based on their other corporate relationships and interactions with Roxane. For example, the jury may misinterpret evidence related to overlapping corporate officers and directors, the functional combination of Roxane and BIPI into an organizational “business unit,” and the sharing of certain services, such as legal, finance and IT between Roxane and BIPI as suggestive of direct liability, even though it does not relate to the pricing and marketing of the Roxane drugs at issue. The only way to prevent the jury from improperly or mistakenly using alter ego evidence to support a direct liability finding is to preclude such evidence from the trial on the underlying FCA issues.

B. Direct Liability Evidence Will Prejudice The Jury Regarding The Veil-Piercing Issues.

Conversely, the issue at stake in the corporate alter-ego claims is whether the overall relationships and interactions between BIC/BIPI and Roxane are sufficient to demonstrate that Roxane lacked corporate independence and that BIC or BIPI acted with fraudulent intent toward Roxane. *See* BIC/BIPI SJ Memo. at 8-14. Detailed evidence of Roxane’s pricing, marketing, sales, or reporting practices is irrelevant, especially evidence unrelated to BIC’s or BIPI’s involvement in those practices (which will constitute the vast majority of the evidence presented on the FCA claims). Moreover the “truth” or “falsity” of the AWP’s for Roxane’s drugs and the nature and amount of alleged damages the Government suffered as a result of Roxane’s allegedly “false” AWP’s is immaterial to the question of whether BIC and BIPI are legally responsible for any FCA liability under an alter ego theory. However, if the veil-piercing claim against BIC and BIPI is tried in the context of the underlying FCA claims against Roxane, the inevitable arguments by the Government that Roxane’s prices were “false” and its conduct constituted “wrongdoing” that caused significant harm and damages to the Medicare and Medicaid programs, will create a significant risk that the jury will find alter-ego liability based on the direct liability theories and allegedly “bad acts” even if the evidence does not support veil piercing.

Because the law strongly disfavors alter-ego liability and imposes “a very high standard” in order to pierce the corporate veil, extra care should be taken to ensure that evidence and arguments related solely to other claims do not prejudice the jury’s veil-piercing decision. *See George Hyman Constr. Co. v. Gateman*, 16 F. Supp. 2d 129, 157 (D. Mass. 1998) (internal citations omitted).

C. A Combined FCA Liability and Veil-Piercing Trial Would Overwhelm And Confuse The Jury and Increase the Risk of Prejudice to BIC and BIPI.

In addition to the danger of FCA evidence inevitably and improperly infiltrating the jury’s determination of the veil-piercing question, and *vice versa*, a trial that combines direct liability and alter-ego claims would also overwhelm and confuse the jury and lead to a greater risk of prejudice especially if the FCA claims against Dey are also part of the trial. As described above, each set of claims is, on its own, complicated, fact-intensive and confusing. *See, e.g., Crane v. Green & Freedman Baking Co.*, 134 F.3d 17, 21 (1st Cir. 1998) (“The legal standard for when it is proper to pierce the corporate veil is notably imprecise and fact-intensive . . . and . . . [t]here is a consensus that the whole area of . . . piercing the corporate veil, is among the most confusing in corporate law.”) Allowing all the FCA claims and the veil-piercing issues to proceed in the same trial will overwhelm the jury with an avalanche of facts and complex issues and inevitably lead to confusion regarding what evidence is relevant to which defendant and which claims. Such added confusion and potential for prejudice is unnecessary in this case because the two sets of claims involve primarily different factual issues and evidence, and could easily be separated into two separate trials before two different juries. *Lisa v. Fournier Marine Corp.*, 866 F.2d 530, 531 (1st Cir. 1989) (“By separating the issues of appellant’s status and the status of the barge from the rest of the case, the court avoided needlessly confusing the jury with multiple, and mutually exclusive, theories of liability.”).

II. SEPARATING THE VEIL-PIERCING ISSUE FOR TRIAL WILL PROMOTE ECONOMY AND EFFICIENCY.

Courts may separate claims for trial to economize and promote efficiency. Fed R. Civ. P. 42(b). In particular, this Court has often separated claims for trial when an issue or claim may be dispositive of the case, rendering other claims moot. *See, e.g., Chapman v. Bernard's Inc.*, 167 F. Supp.2d 406 (D. Mass. 2001) (bifurcating, in a product liability case, issue of whether product at issue was actually manufactured by defendant); *Hewlett-Packard Co.*, 882 F. Supp. at 1157 (bifurcating patent and inequitable conduct claims from antitrust and unfair competition claims for trial, in part because “[a] failure to prove inequitable conduct may eliminate the need to determine the antitrust” claim). This is exactly the case here. If the Government does not prevail on its underlying FCA claims against Roxane, the need to resolve the derivative alter-ego claims seeking to hold BIC and BIPI responsible for Roxane’s liabilities would be eliminated.

Further, because a veil-piercing trial would require presentation of a significant amount of evidence that is irrelevant to the underlying FCA claims, a substantial amount of time, money and judicial resources would be saved in the event the direct liability trial renders the alter-ego issues moot. Even if some overlap in evidence existed between the two claims, perhaps requiring a very few of defendants’ witnesses to testify at two trials, it would not outweigh the advantages of separate trials: the judicial economy of potentially eliminating the need to try an entire claim, and the avoidance of prejudice to BIC and BIPI. *Chapman*, 167 F. Supp. 2d at 417 (“Those advantages are not outweighed by the possibility that the same witnesses may have to testify at both trials.”).

CONCLUSION

For all the foregoing reasons, the Court should grant BIC and BIPI's Motion To Bifurcate The Corporate Veil-Piercing Issues For Trial.

Dated: March 1, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on March 1, 2010, a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ John W. Reale

John W. Reale